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Section II

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K050404

Date	April 19, 2005
Submitter	Intuitive Surgical, Inc. 950 Kifer Road Sunnyvale, CA 94086
ER Number	2955842
Contact	Mike Yramategui Director, Regulatory Affairs Telephone: (408) 523 - 2145 Fax: (408) 523 - 1390 e-mail: mike.yramategui@intusurg.com
Subject Device	Name: Intuitive Surgical℠ da Vinci℠ Surgical System and Endoscopic Instruments Classification Name: System, Surgical, Computer Controlled Instrument (21 CFR 876.1500) Common Name: Endoscopic Instrument Control System, Endoscopic Instruments and Accessories
Predicate Devices	Intuitive Surgical da Vinci Surgical System and Endoscopic Instruments (legally marketed under K990144 / K002489 / K011002 / K011281 / K012833 / K013416 / K021036 / K022574 / K040237 / K040948 / K043153 / K042855 / K050005).
Device Description	This 510(k) is being submitted for an expansion of the Indications for Use to include gynecologic laparoscopic surgical procedures. There are no changes in the design, technology, materials, manufacturing, performance, specifications, and method of use for the da Vinci Surgical System associated with this pre-market notification.

Device Description (continued)

The da Vinci Surgical System consists of two integrated sub-systems as follows:

Intuitive Surgical Endoscopic Instrument Control System: This sub-system is comprised of the Surgeon Console and Patient Side Cart. While seated at the Surgeon Console, the surgeon controls critical aspects of the procedure, including movement of the endoscopic instruments and endoscope, within the operative field. Endoscopic instrument and camera movements are controlled by the surgeon through use of the Master Tool Manipulators (MTM), two hand operated mechanisms residing within the Surgeon Console. The endoscopic instruments are held in a fixed position (with respect to the patient) by either two (or optionally three) unique arms known as Patient Side Manipulators (PSM), which are located on the Patient Side Cart (PSC). The endoscope is also held in a fixed position (with respect to the patient) by another arm, similar to the PSM, known as the Endoscope Camera Manipulator (ECM) and also located on the PSC. Commands from the Surgeon Console are relayed to the PSC, which is located immediately adjacent to the patient, via cables. Instrument and endoscope changes are performed by another provider positioned adjacent to the PSC.

Intuitive Surgical Stereo View Endoscopic System: The endoscopic vision system used with the da Vinci Surgical System, also known as Intuitive Surgical Insite® Vision System, consists of a stereo endoscope, endoscopic camera, and various accessories, including a light source and light guides. The Insite Vision System provides two independent images that are relayed to the viewer located in the Surgeon Console, where they are fused to form a 3-D (or alternatively a 2-D image) image of the surgical field.

Intended Use

The Intuitive Surgical Endoscopic Instrument Control System is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments during gynecologic laparoscopic surgical procedures. It is intended for use by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Comparison to Predicate Device	There are no changes in the design, technology, materials, manufacturing, performance, specifications, and method of use for the da Vinci Surgical System. The expansion of the labeling to include gynecologic laparoscopic surgical procedures is based on the da Vinci Surgical System and endoscopic instruments being currently cleared for performing a full array of surgical tasks across multidisciplinary surgical specialties, and a comparison of surgical tasks performed in cleared procedures to those performed in gynecologic laparoscopic surgical procedures with the system. Additionally, a comparison of endoscopic instruments available on the *da Vinci*® Surgical System with predicate instruments cleared for gynecologic laparoscopic surgical procedures demonstrates substantial equivalence to existing laparoscopic instruments cleared for gynecologic indications.
Technological Characteristics	The technological characteristics of the subject device are the same as for the predicate device (da Vinci Surgical System) cleared to performed similar surgical tasks in other specialties. The primary difference between the subject device and the predicate devices cleared for use in gynecologic laparoscopic surgical procedures is that the subject device provides computerized robotic assistance to precisely manipulate and move the instruments and the predicate devices are hand operated laparoscopic instruments.
Performance Data	Design analysis and comparison, has been conducted to confirm that basic functional characteristics are substantially equivalent to the predicate devices cited, and design validation confirm that there are no new issues of safety or effectiveness for performing surgical tasks in gynecologic laparoscopic surgical procedures.
Conclusion	Based upon the information provided in this pre-market notification, the da Vinci Surgical System described herein has been shown to be substantially equivalent to current legally marketed predicate devices, and the results of the risk analysis and design validation confirm that the there are no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1 2005

Mr. Michael H. Yramategui
Director, Regulatory Affairs
Intuitive Surgical, Inc.
950 Kifer Road
SUNNYVALE CA 94086

Re: K050404
Trade/Device Name: Intuitive Surgical® Endoscopic Instrument Control System
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: II
Product Code: HET
Dated: February 16, 2005
Received: February 17, 2005

Dear Mr. Yramategui:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050404

Device Name: *Intuitive Surgical*® Endoscopic Instrument Control System

Indications For Use:

The *Intuitive Surgical* Endoscopic Instrument Control System is intended to assist in the accurate control of *Intuitive Surgical* Endoscopic Instruments during gynecologic laparoscopic surgical procedures. It is intended for use by trained physicians in an operating room environment in accordance with the representative specific procedures set forth in the Professional Instructions for Use.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050404